

SUNITI JAIN

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A highly organized, pro-active and detail-oriented computer literate with experience in pharmaceutical and IT industry. Excellent planning and problem-solving skills. Ability to complete assignments within critical deadlines and under pressure. A quick learner who combines creative and analytical thinking to improve business processes.

**Experience and skills include:**

- Clinical Data Management
- Database design and Validation
- Clinical Trial Process and GCP/ICH guidelines
- Drug & Device Accountability
- Project Timelines, inventory, Demand & Forecast
- Packaging, labeling and distribution of Clinical Supplies

**Computer Applications:** Oracle Clinical, MS Access, Clintrial, MS Project, Visio, ERP systems, HTML, SQL, Photoshop.

**PROFESSIONAL EXPERIENCE**

**Abbott Labs – Alameda, CA**

**April 07 – July 08**

Clinical Data Specialist: Duties included; assist in the development of Case Report Forms (CRFs), develop and implement data management plan and data entry conventions, write SOPs, communicate with CRAs and clinical sites for data issues and query resolution. Create and maintain Study Binders and study-specific files; provide Data Entry personnel the data conventions and guidelines for each specific study, Data QC and Database locks at the close of study. Write DB specifications and test protocols for database design.

Databases Used: Oracle Clinical and Microsoft Access.

*Reason for leaving – Temporary contract assignment*

**Isis Pharmaceuticals – Carlsbad, CA**

**Nov 06- April 07**

Clinical Supply Chain Coordinator: Duties include creating study supply designs, arranging contract packaging operations, label design, vendor selection, designing IVRS specs, and shipping, tracking and reconciling drug supplies in support of domestic and international regulatory filings along with Budget tracking against purchase orders and invoices. Working closely with Clinical Operations, Regulatory, Materials Management, QA and drug manufacturing teams.

*Reason for leaving – Relocation to northern california*

**Amylin Pharmaceuticals, Inc. – San Diego, CA**

**Aug 06-Sep 06**

Consultant: Clinical Supplies – Assisted Director of Investigational Supplies in preparing various study related documents e.g. CSR, Packaging Requirements, Labels, Randomization List reviews. Coordinated packaging and labeling activities with 3rd party vendors including shipments of DS, DP etc.

*Reason for Leaving – Short term contract assignment.*

**Elan – San Diego, CA**

**Jun 05–Nov 05**

Clinical Data Assistant – Clinical data entry using Clintrial. Preparing data transmittal pages, scanning, separating subject packets, filing etc.

*Reason for Leaving – Temporary contract assignment.*

**Plus Orthopedics – San Diego, CA**

**Feb 05 – May 05**

Clinical Assistant: Assisted with tasks related to organizing Clinical data, device inventory and accountability, change notices, CRFs. Designed forms and reports to facilitate tracking and analysis of clinical records and devices. Assisted in writing and executing test cases for validation of company's ERP and PDA scanning system. Optimized data entry and tracking using excel and MSACCESS.

*Reason for Leaving – Temporary contract assignment.*

**Pfizer, Inc. – La Jolla, CA****Oct 01- Oct. 2004**

Project Coordinator: Strategic planning, management, and coordination of Clinical Trial Materials requiring regular communication with Clinical Research, Pharm Sci, Regulatory, QA and Materials Management. Tracking and record keeping of all study related information including Investigators, Sites, Patient enrollment, Randomization, Regulatory Approvals, Drug Releases, and distribution to meet project timelines. GMP and SOP Training Contact for the department.

Computer Support: Supported deployment of an electronic system designed for managing Clinical supplies. Responsibilities: Support the Local Admin functions, revise SOPS, help users with daily inquiries, user training, write and execute test protocols, design reports, forms and work processes for efficient utilization of the database.

*Reason for Leaving – Reduction in work force.*

**Selected Accomplishments at Pfizer:**

- Key contributor in cross departmental training to expedite the transition from legacy paper system to electronic database.
- Developed work processes to optimize efficiency of resources and systems utilization.
- Designed forms and reports to standardize work processes across 5 global Pfizer sites. Took lead role in designing 'Customs Document' forms (Performa Invoice) addressing issues of all sites.
- Set up a system to organize and archive records of closed studies
- Received 4 "On the Spot" rewards for timely delivery of portfolio, successful launching of projects, and contribution in audit preparations.

**Quality Advisors, Inc. - San Diego, CA****1995 – 2001**

Office Manager: Provided administrative, operational and marketing support. Prepared presentations, spreadsheets, and writing departmental procedures for clients. Coordinated service and marketing seminars on ISO 9000 standards.

- Set up various reporting systems for daily operation, marketing and financials using Access and Excel.
- Assisted in the design of company web page using HTML and FrontPage.
- Supported accounting by performing account reconciliation, preparing proposals, invoices, expense reports and financial statements using QuickBooks under the supervision of an outside accountant.

**Hill Top Nursing Home - Escondido, CA****1993 – 1995**

Licensed Vocation Nurse

Duties included patient assessment, medication and treatments, daily charting and reporting to the doctors. Performed inventory and kept records of medical supplies and drugs. Communicated with patients and their families.

**Convergent Technologies – San Jose, CA****1984 – 1986**

QC Supervisor– Supervised department of Incoming Inspection of electronic and mechanical components for computer assembly.

**EDUCATION**

- BS in Computer Information Systems (2008) - Excelsior College, Albany, NY, 2008
- Completed Courses related to Clinical Trials: Regulatory Compliance for Biologics and Drugs; Clinical Data Management, Intro to GMP, GCPs, Nuts & Bolts of Clinical Trials, You Are the Auditor; Documentation Skills; Preparation, Packaging and Labeling of Clinical Supplies. Project Management Boot Camp.
- Vocational Nurse (LVN) – Maric College, San Marcos, CA
- Bachelor of Arts - Punjabi University, India

**MEMBERSHIPS**

- Society of Clinical Data Management